



# USAF Legislative Liaison Congressional Hearing Resume 106<sup>th</sup> Congress; Second Session

**SUBJECT:** Anthrax Vaccine Immunization Program - What Have We Learned

**COMMITTEE:** House Committee on Government Reform

**CHAIRMAN:** The Honorable Dan Burton

**DATE:** 11 Oct 00

**MEMBERS PRESENT (bold face):**

## REPUBLICANS

<b>Dan Burton, Ch (IN)</b>	Marshall Stanford (SC)
<b>Constance A. Morella (MD)</b>	Bobb Barr (GA)
<b>Christopher Shays (CT)</b>	Dan Miller (FL)
<b>Ileana Ros-Lehtinen (FL)</b>	Asa Hutchinson (AR)
John M. McHugh (NY)	<b>Lee Terry (NE)</b>
<b>Stephen Horn (CA)</b>	Judy Biggert (IL)
John L. Mica (FL)	Greg Walden (OR)
Thomas M. Davis III (VA)	Doge Ose (CA)
David M. McIntosh (IN)	Paul Ryan (WI)
<b>Mark E. Souder (IN)</b>	<b>Helen Chenoweth-Hage (ID)</b>
Joe Scarborough (FL)	David Vitter (LA)
Steven C. LaTourette (OH)	<b>Benjamin Gillman (NY)</b>

## DEMOCRATS

Henry Waxman, Ranking (CA)	Rod R. Blagojevich (IL)
Tom Lantos (CA)	Danny K. Davis (IL)
Robert E. Wise, Jr. (WV)	<b>John F. Tierney (MA)</b>
Major R. Owens (NY)	Jim Turner (TX)
Edolphus Towns (NY)	Thomas H. Allen (ME)
Paul E. Kanjorski (PA)	Harold E. Ford, Jr. (TN)
Patsy T. Mink (HI)	<b>Janice D. Schakowsky (IL)</b>
Carolyn B. Maloney (NY)	
<b>Elenor Holmes Norton (DC)</b>	
Chaka Fattah (PA)	
<b>Elijah E. Cummings (MD)</b>	
<b>Dennis J. Kucinich (OH)</b>	

**Visitors:**

**Walter B. Jones (R-NC), HASC**

**John M. Shimius (R-IL), Commerce**

**WITNESSES:**

## PANEL 1

- Tom Heemstra
- Dan Marohn
- Pat Ross
- R. Steven Porter, Virtual Drug Development, Inc., Brentwood, TN

## **PANEL 2**

- Maj Gen Randall L. West, Sr. Advisor to the DEPSECDEF for Anthrax and Biological Defense
  - Col Randolph, Director, AVIP Agency
- Maj Gen Paul A. Weaver, Jr., Director, National Guard Bureau
- Mr. Kwai-Cheung Chan, GAO
  - Mr. Wicker, GAO
  - Dr. Sharma, GAO

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## EXTENDED SUMMARY

This was a very acrimonious hearing. All members present were very critical of the program. All expressed their belief that in view of the GAO testimony, the testimony of the Panel 1 witnesses, and previous hearings, that the DoD should end, make voluntary, or at least seriously review the wisdom of the program. Mr. Burton and Mr. Shays were especially critical. Both accusing DoD witnesses of being disingenuous at best and come just short of accusing Gen Weaver of deliberately lying to Congress and to the Guard about 1) the impact of the AVIP on retention in the Guard, and 2) his promise at a previous hearing to find out if anthrax was a reason for resignations from the Guard. They also mentioned Mr. Cragin's previous testimony that no Guardsman or Reservist would be punished for refusing the AVA.

### Panel 1:

The first three of these witnesses were all former ANG members, and all are commercial pilots. All had refused to take the anthrax shots. All stated they had been either fired, grounded, threatened with judicial or non-judicial punishment, jail, fines, etc. The all stated they knew of many other ANG members who had left the Guard rather than take these shots. In response to Mr. Burton's questions, they all said they either knew of or personally knew members who had suffered adverse reactions to the shots. All stated that the AVIP had destroyed trust and morale in the ANG. These former guardsmen stated that due to fear of reprisals, guardsmen were not forthcoming as to their real reasons for separating, and many also hid vaccine-associated illnesses from medics for the same reason. During this session Mr. Burton made several references to the UCMJ and the penalties for lying under oath. In this connection, Mr. Burton or Mr. Shays made specific reference to Gen Weaver's testimony at previous hearings that guardsmen who refused to take the shot would not be punished (but permitted to resign), and that there was only one resignation due to anthrax. He then observed that clearly Guardsmen were being punished.

Mr. Porter represents a company that is developing a novel antibiotic targeting a bacterial enzyme that he says shows good in vitro activity against all strains of anthrax tests. Work thus far has been supported by DARPA and by USAMIID. Asked for an additional \$17M to complete the work, and estimated it could be ready for market in 4 years.

### Panel 2:

Mr. Chan summarized preliminary findings of a GAO survey that went out to a random sample of 1253 flight crew members of the ANG and AF Reserve (66% return rate). Survey results indicated that 25% of those who had either separated or changed positions in the Guard or Reserve did so because of anthrax (single most common reason), and that 43% of them would come back if the program was ended. 18% of those still on flight status in the Guard or Reserve stated they intended to leave within 6 months, and more than 60% of them stated that anthrax was the reason. 86% of survey respondents indicated they had suffered from significant local or systemic reactions to the shot. 60% of those with reactions said they did not report them to medical authorities, and 49% of them stated they did not report because of fear of repercussions. 71% stated they were unaware of the Vaccine Adverse Events Reporting System (VAERS).

GAO also presented data and testified that service members have a profound lack of faith in the program and a deep lack of trust of DoD leadership on this issue. **Mr. Chan repeated unsubstantiated allegations made to him during GAO visits to AF bases that commanders were no longer sending troops with suspected adverse reactions to the shot to Walter Reed Army Medical Center because Walter Reed AMC was giving medical exemptions from further shots. Instead, they were sending the troops to Andrews AFB because fewer deferments were given there. Mr Burton called this "practically criminal."**

Gen West began by saying that he was not going to repeat previous testimony to this committee of comment on the GAO report, because he had not seen the GAO report yet. He was interrupted by Mr. Shays and castigated for failing to be prepared for the hearing by not getting and reviewing the GAO testimony ahead of time. Mr. Chan, in response to questions from Mr. Burton, said GAO had given a

detailed briefing to DoD representatives the week previously, including Gen West. Gen West replied that he had been back-briefed by his staff, but that was not the same as having the GAO report and he could not respond to the report until it was released to the DoD. Mr. Shays said he wanted to know Gen West's personal opinions. Mr. Burton added that he hoped that in future Gen West would be better served by his staff, and that he expected that superior officers would be briefed by their staffs on important matters prior to hearings.

Gen West then stated that the program was necessary because the threat was real, that we knew the agent had been deployed in Iraq (but not employed), and that the vaccine was the best available protection. Mr. Shays asked Gen West if he or any of his troops had actually seen any anthrax weapons. When he was told that this was based on intelligence sources, Mr. Shays expressed some doubt as to the veracity of the assertion that weaponized anthrax was present on the battlefield during Desert Storm. He cited previous problems with DoD assertions about chemical weapons exposures during that same conflict. Gen West suggested that the classified threat briefing given by the CIA would provide the evidence that Mr. Shays wanted. Mr. Shays said he would take that briefing and requested that Gen West accompany him.

Mr. Burton, Mr. Shays, and other members questioned whether people who had bad reactions to the shot should be exempt from additional immunizations. Mr. Burton stated that people who refused shots based on previous bad reactions were being punished for refusing to take them. Gen West said that people who had more than the expected minor reactions should be medically deferred from additional shots until the cause of the illness or reaction was determined. He expressed great concern about the numbers reported by GAO, and said it meant the DoD had to do a much better job at educating about the vaccine and about the threat. He said losing even a single troop because of disinformation about vaccine safety or the need for it was tragic. Mr. Burton observed the irony in the DoD complaining about disinformation on the part of AVIP opponents. Finally, Gen West was questioned about squalene in the vaccine, about the quality, safety and efficacy of the vaccine, and about Bioprot.

Gen Weaver testified that overall retention in the Guard was up compared to last year, and was in fact the best of all the Services (attrition rate 10.7% from FY00 vs. 11+% in FY99). He had asked ANG commanders to conduct exit surveys in Dec 99. While there might be some reluctance on the part of some members to put anthrax down as the reason for separating, the data simply did not support the contention that anthrax was causing a mass exodus from the ANG.

Gen Weaver was then sharply rebuked by Mr. Shays over several issues. At one point he was asked by Mr. Burton or Mr. Shays (have to check the transcript) if he was aware of the UCMJ penalty for lying under oath. The three main issues for Gen Weaver were as follows:

First was General Weaver's statement in previous hearings that only one Guardsman had resigned due to anthrax. In the first of two video clips shown, Gen Weaver testified before Mr Shays at a hearing last year that to his knowledge only one guardsman had resigned over the shot. In a second video clip, taken from a closed-circuit briefing to Guardsman, Gen Weaver was asked via fax if he had been aware of Guard separations at several bases when he had testified before Congress. Gen Weaver responded that he had testified that he was not talking about people who had no commitment and who walked. Mr. Burton had his staff reviewed the testimony and stated there was no reference in it to "other people walking." Mr. Shays demanded an explanation for the discrepancy. Mr. Burton stated the troops felt they had been misled by Gen Weaver during that closed circuit briefing. Mr. Burton then criticized Gen Weaver's previous testimony as disingenuous, hair splitting, and a deliberate attempt to mislead, especially given his promise find out the facts. He pointed out that anonymous DoD surveys sent to Guardsmen/Reservists and their spouses did not even mention anthrax. He believed this shows the DoD simply does not want to know the truth.

The second issue was Gen Weaver's assertion that the numbers did not support the view that anthrax was causing the exodus of experienced pilots from the guard (based on steady state numbers over the past few years). Mr Shays questioned Gen Weaver, asking him if he was testifying "under oath" that the ANG was not losing people and replacing them with less experienced people (who require lots of

time and money to train). Gen Weaver admitted that while overall numbers were fairly constant, over the past few years the trend was for increasing resignations and decreasing retirements.

Finally, Mr. Shays demanded to know whether Gen Weaver had directed that people be asked specifically about anthrax when they separated, has he had promised to do at his last hearing. Gen Weaver admitted that he had not, but had requested ANG commanders to conduct exit interviews and report on reasons give for separation. Mr. Shays asked for a copy of the document requesting that exit interview data be reported. He then pointedly asked what date he'd see on that letter, and asked several times if he'd see it that it was dated from last year.

During the Q&A, several other Members stated their view that it was time for the DoD to reevaluate their insistence on continuing this program while people were suffering, maybe dying, and experienced pilots were fleeing the service rather than get the anthrax vaccination.

The meeting closed with Mr. Burton saying he has subpoena power, was going to subpoena anthrax shot records from Desert Storm, intended to recall Mr. Cragin to testify, and had the authority to call hearings even after Congress adjourned. He said he intended to order GAO to broaden their inquiries to include the active duty force.

**BOTTOM LINE:** Committee members present believe the vaccine is neither safe nor effective. Committee members present believe DoD did not, and does not, want to know the truth about the impact of this vaccine on either the health of troops or retention. Mr. Shays and Mr. Burton believe that DoD has deliberately misled, if not lied outright, to both Congress and Servicemembers on these issues. Finally, the committee members present all felt that the program was causing a crisis of confidence in military leadership, and should be stopped on that basis alone.

The hearing began at 1005

### **Mr. Burton's Opening Statement**

- Summarized the testimony from the 3 Oct hearing, concentrating on the first panel. Stated that four members were injured, maybe never to recover, and that two deaths were blamed by the witnesses on the anthrax absorbed vaccine (AVA).
- Previewed the testimony of the panel 1 witnesses and the GAO from the current hearing
- Discussed Mr. Cragin's testimony at a previous hearing when he said that, because they are volunteers, no Guardsman or Reservist would be punished for refusing the AVA (could just resign, presumably). Pointed out that the witnesses today had been punished for just this reason.
- Stated his belief that Guard and Reserve was losing lots of experience pilots due to the AVIP
- Charged the DoD with ignoring previous GAO reports about the AVIP, and by denigrating or attacking anyone who dares oppose it
- AVIP is the wrong approach for protecting our troops, and advocated better suits, masks, and detectors.

### **Mr. Kucinich's Opening Statement (for Mr. Waxman)**

- Thanked the Committee for the hearing, which addressed important and serious questions
- Looked forward to hearing the testimony

### **Mr. Shays' Opening Statement**

- DoD has stated, without any systematic collection of evidence, that the impact of AVIP on retention is negligible. DoD continues to ignore the substantial impact on ARC readiness and morale
- There has been a purposeful failure to collect this information, and deliberate attempts to misinform by the DoD

- AVIP is a force protection experiment
- Stated that DoD has not told the truth to the Committee, that AVIP has destroyed morale and readiness, and must be stopped.

#### **Mr. Gillman's Opening Statement**

- Thanked the committee for the hearings and reviewed his role in requesting the GAO study
- Stated that pilots are leaving in "droves," but the DoD insists it isn't happening
- Stated that the military depends on the ARC, all citizen volunteers, and the program thus threaten our national readiness in a very direct way
- Program began with good intentions, but was too hasty, and now the Pentagon is hiding the true impact of adverse reactions.
- Alleged DoD did not reply to committee letters/reports on adverse reactions, and how they claim to have lost medical records (utters with heavy disbelief evident, apparently referring to a report that DoD can't locate AVA immunization records from Desert Storm).
- DoD has consistently underplayed AVIP program impacts and deceived the subcommittee. Accordingly, called for an independent review of the program

#### **Mr. Souder's Opening Statement**

- Discussed the courage of the Guardsman at Ft. Wayne, both in combat over Kosovo.
- Spoke of retaliation, not only against individual members but also wings and bases. Specifically, mentioned attempts to move the F-16 squadrons from Ft. Wayne, and clearly linked vaccine refusals with this proposed action (threat implied).
- Believed ANG commanders at Ft. Wayne and elsewhere were in a tough spot--must support a program with is causing them lots of problems.
- Stated that he has been contacted by many constituent in the ARC who are legitimately concerned about Gulf War Syndrome (GWS) and the role that AVA and other shots may have played in it. They are concerned about loss of livelihood while the government is concerned only about risk aversion.
- Questioned the wisdom of making this a mandatory immunization program

### **Panel One Statements**

#### **Mr. Heemstra's Statement**

- Is speaking on behalf of other also believe the program is wrong but fear reprisals/repurcussions
- Reviewed his military career culminating in his refusal and separation from service
- Stated that ARC has lost 12% (260) of pilots so far, and predicted it would reach 2000 resignations. Reminded the committee that it takes years and millions of dollars to make a fully combat ready pilot.
- DoD is in denial about the "large number of people who have voted with their feet."
- In his unit they replace 21 experience pilots with 14 new people who will require lots of training. Replacement training costs will be 10x the cost of the entire AVIP. If this happens on a grand scale the impact will be enormous
- DoD has betrayed its trust, lied to troops, the GAO, and this committee. Have coerced and punished to make AVIP happen. As an example, stated he was grounded illegally for his refusal
- Stated that AVA is an investigational new drug (IND), but DoD acts as if it is not and the program is based on corruption and callous disregard for men and women in uniform
- Called on the Committee to restore the faith, force acquisition of a safe and effective vaccine for force protection, and grant legal amnesty to all service members who have been punished for refusing to take the shots.

#### **Mr. Marohn's Statement**

- Stated that he was speaking for those afraid to do so



- Reviewed his career, and explained he had a service commitment that precluded his resignation.
- After he was threatened, he sought out and was briefed by Dr. Nass about the true dangers of the AVA
- Now has grave concerns about the integrity of leadership
- He was grounded 1 month before the “deadline,” and other actions against him have been similarly illegal. Case is now pending based on appeal based on program slowdown
- AVIP has harmed people and their careers, and ask for the Committee to act

#### **Mr. Ross’ Statement**

- Summarized loss of combat ready pilots due to AVIP, saying that 25-50% of pilots bail when deployment of the Guard unit forces the shots, with persecution and harassment of those that remain.
- Reviewed some statistics, including that 25% of pilots were lost in Connecticut. Stated that even when shot if voluntary, people get punished for not volunteering.
- Noted that training costs lost when pilots separate, and cost of training replaces, is 10x more than the cost of the AVIP program. Observed it also hits the enlistee force.
- Last year losses due to this program totalled 260 pilots, a fact not reported by DoD or the AF.
- Stated people are leaving due to lack of trust in leadership, which reduces morale and retention. People question whether the vaccine is safe and effective, and whether they will receive adequate medical care if they get ill.
- Called for the program to be halted until concerns of Congress are met and a safe and effective vaccine assured.

#### **Mr. Porter’s Statement**

- Mr. Porter described the company’s mission, structure, and portfolio. Stated the virtual nature of the company promised to cut drug development costs by 25% and approval time by 50%
- Novel antibiotic with activity against anthrax, targets a bacterial enzyme (NAD synthase) and so should have very acceptable safety profile and work against all strains of anthrax (including engineered varieties). A small molecule, easy and cheap to synthesize in quantity on demand.
- Proposed the antibiotic would be used prophylactically (before exposure), and continued for 60 days post exposure to protect troops.
- Reviewed the status of the program. DARPA has already invested \$6M, USAMRIID has sponsored some in vitro testing against anthrax isolates. Requested another \$11M to complete all biosynthetic work
- Discussed future plans for animal and phase I clinical (safety) trials, as well as cooperation with FDA to establish acceptable surrogate evidence for efficacy in humans.
- Hoped to have approval in 4 years.

#### **Panel 1 Questions and Comments**

CM Burton asked Mr. Heemstra if he had been retaliated against. Mr. Heemstra replied that he had been grounded arbitrarily. Upon further questioning from the Chairman, Mr. Heemstra explained how important the ANG is to readiness, and how AVIP was driving pilots out of the Guard. Said the Guard is already 2000 pilots short and predicted that 2000 pilots would eventually leave.

CM Burton asked Mr. Marohn why he didn’t just resign. After being informed he had a 7-year ADSC, Mr. Burton asked if anyone had informed him officially of the slowdown policy. Mr. Marohn said only by word or mouth, “happenstance.” Finally, Mr. Burton asked if Mr. Cragin’s statement that reservists would not be punished was accurate. Mr. Marohn said no. Mr. Burton said this would be a QFR for Mr. Cragin.

Mr. Ross responded to Mr. Burton's question saying the DoD was incorrect in saying that only a small number were resigning over the AVIP, that 20-50% was more accurate. **Mr. Burton stated that under the UCMJ false making false statements lead to court martial, and asked if he thought that they (senior officers making these statements) should be punished. Mr. Ross responded that he thought they could be.**

Mr. Burton developed the theme that since many guard pilots are airline pilots, medical problems caused by the AVA, such as dizziness or numbness of an extremity, represented a threat to public safety.

In response to questions by CM Cummings and CW Schakowsky, Mr. Ross stated that exit interviews might not reveal an exact reason pilots were leaving because they feared retribution, especially if leaving for a different job in the Guard or transfer to the Reserve. Ms. Schakowsky asked if the fear of retribution was well founded, that perhaps it was just a rumor mill kind of thing. Mr. Marohn stated that in his case at least it was very real.

CM Souder asked the panelists what percentage of ANG pilots worked for the airlines. Answer: about 75%. CM Souder then asked if the problem (with knowing the impact of AVIP on retention) was an inaccurate database. He added that the DoD should track each and every shot and every medical result, even if not known to be vaccine associated.

Mr. Ross offered that command support of the AVIP was due in part to fear of being held responsible in the event of a terrorist attack (as in Khobar Towers). In response to additional questioning, Mr. Ross said he thought that making the program voluntary would not blemish the image of the ANG. They were different from the active component, had full time jobs outside, and could be treated differently.

**CW Schakowsky stated she was very uncomfortable with the way that service members were being treated. Her husband was a pilot and she knew that pilots want to fly, therefore she understands the pain the witnesses feel about being grounded. She felt the DoD was not seeking the truth, that there were few studies (on safety and efficacy), problems with the manufacturer. She is increasingly skeptical about the wisdom of the AVIP.**

Mr. Horn asked the witnesses how high up the vaccinations went? All responded that to their knowledge everyone who was deploying was required to take the shot. In addition, commanders had been asked to volunteer to take the shot (even if not deploying). **Mr. Heemstra added that he had heard of a Guard unit in NY in which 90% of pilots threatened resignation, and that the Guard Bureau exempted all of them somehow. This could not be confirmed. Gen Weaver was asked to provide information about any exemptions granted by the Guard Bureau.**

CW Morella stated that the GAO report underscores concerns about vaccine safety and efficacy. She said the Pentagon has obviously failed to convince the very people they are trying to protect. She then asked Mr. Porter questions about the antibiotic his company was developing. CM Gillman also addressed questions to Mr. Porter. In response, Mr. Porter said it would take \$17M to fully develop, that they'd be working with the FDA to get fast track approval, and that it would be used prophylactically and then be taken for 60 days after exposure. **Asked specifically what he thought about the current anthrax vaccine, Mr. Porter said he thought it probably was pretty much like other vaccines (1% risk of adverse reactions), and that a risk-benefit calculation had to be made. In the meantime, he suggested DoD could use protective clothing, detectors, ciprofloxacin, and target use of the existing vaccine to the populations at highest risk.**



CM Moralla then asked as an open question what the panel witnesses believe the committee should do. Witnesses stated the program should be made voluntary, a moratorium declared until all Committee questions were answered, and should only be done with a new drug or vaccine that has been proven to be safe.

CM Jones asked witnesses about how much they were told about the vaccine and when they were told. Mr. Heemstra heard nothing from the DoD until after he had already spoken to Dr. Nass about it in March 98. Further, he stated that the so-called expert sent by DoD to give the briefing, a microbiologist/epidemiologist from Colorado, was not credible. Mr. Marohn said he got no official briefing until his unit got the order to get the shots, and what DoD said was contrary to what he had found out for himself. Mr. Ross said that Battlecreek had already had 12 enlisted technicians get the shots and get sick before the flying community was ordered to get the shots in Dec 99.

CM Shays discussed Mr. Heemstra's previous testimony before the subcommittee, making special note of the contention that "we are guinea pigs." He talked about departure from the FDA approved shot-schedule due to slow down, and previous testimony from Mr. Cragin and Gen Weaver. He asked that the two DoD surveys be entered into the record, and observed that despite Gen Weaver's promise to do so, there were no specific anthrax questions in the survey. He also submitted for the record the "obnoxious" letter to the committee from Mr. Cragin (22 Oct 99 response to committee letter of 7 Oct 00), the letter to Gen Weaver (3 Nov 99), and Gen Weaver's response (10 Nov 00)

## **PANEL 2**

### **Mr. Chan's Statement**

- Testified about preliminary results of survey. Randomly selected 1200+ aircrew members from a Guard and Reserve population of about 13,000, with a 66% return rate. Results were then weighted to represent current force structure.
- Preliminary findings were that about 25% of aircrew leaving the guard and reserves did so because of anthrax. Most people had bad local or systemic reactions (86%) but did not report them to military medics (60%) for fear of repercussions (48%). Further, there was widespread distrust not only of this program in particular, but of all drugs and vaccines used for force protections against CBW, and lack of trust in military leadership on this issue as well.

### **Gen West's Statement**

- Stated he would not repeat previous statements, nor comment on GAO report which has not yet been released. Gen West was then interrupted by Mr. Shays and scolded for being unprepared for the hearing ("I can't believe you didn't want to see their testimony"). Gen West said that he had been briefed by his staff but that was not the same thing as seeing the report, and without it could not offer an official DoD position. Mr. Shays called that response disingenuous and part of a pattern. Mr. Burton added that he found it troubling that Gen West did not get a full briefing by his staff, and hoped that in future he would.
- Stated for the record that he had never made any false statements to the Committee, never lied, never called anyone a malingerer
- When he took the job he knew the program was contentious, and made it his business to go to the opposition, those who were ill, visit the web sites, etc.
- After finding out all he could about it, discussing the findings and validating the threat, was convinced that AVIP was the right thing to do.
- Stated that he was on the ground in Iraq, and was chilled when he found that Iraq had deployed the anthrax weapon and had given field commanders operational directions for its use.
- Program was launched by JCS on CINC recommendations only after experts at the FDA, CDC, NIH, etc. all said the vaccine was safe and effective.

- DoD did respond to the Committee's letter, Mr. Gillman, a 70 page response full of science
- Am very concerned about the numbers mentioned in the first panel and the GAO testimony. Our data shows that attrition in the ARC is not higher now than in 1998, a discrepancy I intend to investigate.
- Antibiotics are good, but only while you are taking them, and that's not good enough. If we stop the program we will send good people in harms way without the best protection available.

### **Gen Weaver's Statement**

- Guard recruiting, retention and readiness (RRR) directly affects overall AF as we deploy with the AEFs. 50% of Guard will deploy in the next 30 months, providing 20% of the aircraft and 8% of the support.
- Attrition rate for FY00 is 10.7%, down from 11+% in FY99. This is the lowest rate of all the services
- Since Dec 99 have asked commanders to report results of exit surveys. These reports do not agree with previous testimony, though we acknowledge there may be some underreporting on the exit surveys.
- We owe our Guardsmen the force protection afforded by this vaccine.

### **Panel 2 Questions and Comments**

Mr. Shays asked Gen West, given that Iraq had anthrax, how they intended to protect their own troop. Gen West said he they had protective clothing and masks, but they would not have been fully protected. Mr. Shays asked if the Iraqi troops had been vaccinated, if all of them were vaccinated. Gen West said he didn't know, but believed some of them were vaccinated with the Russian vaccine. Mr. Shays said that was the short of thing he's want to know under the same situation, and said the Gen West should have known these things.

Mr Burton asked Gen Weaver why the DoD surveys did not ask specifically about anthrax. Gen Weaver said the survey was designed to solicit their answers, not suggest an answer. Mr. Burton asked why DoD did not include the anthrax addendum suggested by the Committee, and then stated that it should have been designed into the survey from the beginning--had been in development for a year and DoD knew the question was important.

Mr. Shays asked Gen West if he or his troops had actually found any weaponized anthrax on the battlefield. Gen West said no, that that information came from intelligence sources, enemy document seized, etc. Mr. Shays expressed doubt as to the veracity of those reports, citing DoD's record on admitting troop exposure to chemical weapons. Added that he was not questioning Gen West's integrity, but believed that his enthusiasim for th program had blinded him.

Mr. Shays asked Gen West why FDA turned down DoD on their application to use AVA as an IND? Gen West said to his knowledge that was not true, and Mr. Shays admitted he could not confirm that either. Mr. Chan told Mr. Shays that FDA had received a request to change the labeling so that it specifically mentioned use of the vaccine for inhalation anthrax, but that FDA had not yet acted on it. Dr. Sharma (FDA) explained that the current label does not specify a route of expose at all, and that licensing the vaccine for inhalation anthrax would require additional data. However, FDA did write to DoD saying that its use to prevent inhalation anthrax was "not inconsistent" with the current product labeling. Mr; Chan added that this letter from FDA did not constitute an official FDA opinion on the matter. Gen West said that once FDA had said it was Okto use a labeled as labeled, DoD did not pursue the labeling change further.

Mr. Shays then showed two video clips of Gen Weaver: on testifying before Mr. Shays subcommittee about a year ago, and one video clip from a closed circuit telecast to ANG commanders a few months later. In the first clip Gen Weaver stated that only one Guardsman had refused the shot. In the second

Gen Weaver responded to a faxed question asking him if, when testifying before congress, he was unaware of the refusals in CT and elsewhere. In the clip, Gen Weaver said that he had also testified that there were people who had no commitment and who simply walked, and that these were not considered refusals. Mr. Shays said one or both statements were inaccurate, and Mr. Burton added that his staff could find no reference to people “with no commitment walking” in the previous testimony. Gen Weaver was asked if he knew what the penalty was for giving false testimony. Mr. Burton said troops felt misled by that closed-circuit briefing. Mr. Burton stated the previous testimony was disingenuous, hair-splitting, and a deliberate attempt to mislead.

Gen Weaver stated that the numbers on attrition and the exit surveys don’t support a mass exodus due to anthrax. Mr. Burton argued that the guard numbers masked the fact that they were hiring inexperienced pilots to replace the ones leaving. Mr. Shays pointed out that in fact retirements were down and resignations were up over the past few years, and Gen Weaver agreed. Mr. Shays agreed that there were a myriad of reasons why people might leave the Guard, but said it was a shame if Anthrax tipped the scales.

Mr. Shays reminded Gen Weaver of his promise at the previous hearing to find out if anthrax was causing people to leave the Guard. Gen Weaver explained he could only ask the state Adjutants General to conduct the exit survey, he did not have the authority to order them to do it. Mr. Shays then demanded to know if Gen Weaver had specifically asked about anthrax, and asked to see the document making that request. Gen Weaver admitted that he asked for data from the exit surveys, but the surveys did not specifically ask about anthrax.

Mr. Burton addressed the issue of squalene in the anthrax vaccine, and that the FDA had just found traces after DoD said there was none present. He asked if DoD knew of the medical opinion offered by a Dr. Lewis at Baylor University that squalene might affect the immune response in the doses found. Dr. Sharma added that GAO had found one reference to a Canadian study in animals showing that squalene might harm the immune system. Gen West reiterated the FDA opinion that it was present in trace amounts as a normal biological component, had not been deliberately added as an adjuvant, and would have to be present at much higher concentrations (2,000,000x) to serve as an adjuvant.

Mr. Burton asked if the AVA would be effective against all known strains of anthrax, and did Gen West know how many strains there were? Dr. Chan quoted an article by someone at USAMRIID mentioning 32 strains, and that in a guinea pig model it failed to protect against 8 of them. Gen West responded that scientists believe the guinea pig model is not the best model for evaluating efficacy in man.

CM Cumming asked, based on testimony from the 3 Oct hearing, pictures of Kevin Anderson with his skin missing, that we ought to revisit this whole vaccine policy. Gen Weaver said that the decision was based on the threat and the best medical opinion, and that he admitted we did not do a good job of educating our troops at first. We’re doing a much better job and have “turned the corner.” Gen West added that both medical and civilian medical experts have stated that Kevin Anderson’s illness was not due to the vaccine, and the committee knew it and showed those pictures again anyway.

In response to questions from Mr. Cummings, Mr. Chan said that the VAERS data was very incomplete, and thus insufficient to come to the conclusion that the vaccine was safe. Members added that stories of people getting shots despite previous bad reactions, fear to report such reactions, and profound lack of trust were very troubling. **Mr. Cummings asked the rhetorical question just what kind of evidence would it take to convince you we need to reevaluate this program? How many people need to suffer and die? How is this affecting morale?** Gen West responded that we need to have that trust and are working very hard to improve AVIP education, make VAERS work better, and ensure members with

reactions greater than the expected minor ones are medically evaluated before any more shots are given.

Mr. Burton asked Mr. Chan if GAO had looked at the active duty forces as well. Mr. Chan replied only indirectly, but the issues were consistent. Mr. Wicker added that troops everywhere complained that communications was only top-down. If questions or concerns are raised up the chain they are either ignored or attacked. As a result people do not trust the DoD information about the program.

Mr. Burton asked why tainted vaccine was being retained by the military. Gen West replied that only FDA approved and released vaccine was being used. There was a lot that had less preservative in it, but was still pure and sterile. The DoD had decided to keep this on hand in case anthrax was used somewhere and it was the only vaccine available. However, it was not being used.

Mr. Shays commented on Dr. Walker's testimony from the 3 Oct hearing, specifically that 1) a small number of people are expected to have bad reactions so DoD should not be surprised when they do, and 2) it is bad medical practice to compel vaccination. Asked Gen West why we are forcing people who have bad reactions to take more shots? Gen West reiterated that was counter to AVIP policy and should not be happening. Shays countered that it was happening. Dr. Chan added that he had heard, but not substantiated, that some bases were no longer sending people with suspected vaccine reactions to Walter Reed Army Medical Center (WRAMC), because WRAMC granted too many medical deferrals. Instead troops were being sent to Andrews because Andrews did not give medical deferrals. Mr. Burton said this "bordered on the criminal." Gen West said it should not be happening and is counter to all directives.

**Gen West stated he was very sorry that members of the Guard and Reserves had left, sorry they've been misled by the opposition. Mr. Shays responded he was concerned about the use of the term opposition, that the first panelists were members of the military family. Also he asked if they had been misled, or has Congress been misled? We've had too many witnesses saying they were told to take the shot, not getting enough care, told they were not having an adverse reaction. It is you who have misled.**

Mr. Cummings asked if there was anything that tells troops to see a doctor if they have a significant reaction or that if they do they don't have to get another shot? Col Randolph answered for Gen West. Described the AVIP quadfold given to everyone before the first shot which explains symptoms, VAERS reporting procedures, gives the FDA toll-free number and useful web addresses as well. Stated that the VAERS info was not on the original card, but was added around the fall of 1998. CM Burton asked again if it said that they didn't have to get another shot if they had a bad reaction, and then asked that all versions of the quadfold and information cards be provided to the Committee.

Mr. Burton closed the hearing by saying he would have all the DoD witnesses back again, including Mr. Cragin. He still had subpoena authority and could have hearings after this Congress adjourned. He intended to subpoena all records pertaining to AVA shots given during the Gulf War. He also told Mr. Chan he intended to ask the GAO to broaden the scope of their study to include the active duty.

The hearing adjourned at 1635.

#### **TASKERS:**

1) Gen Weaver to provide the Committee with the document requesting ANG commanders to report results of exit surveys

- 2) DoD to provide Committee with the number of civilian technicians in the ARC that have left due to anthrax.
- 3) CFR for Mr. Cragin: Please comment on your previous testimony that because they are volunteers, reservists would not be punished for refusing anthrax vaccination
- 4) Gen Weaver to inform the Committee of any exceptions to policy re: requirement for the anthrax vaccine (relates to the story about the unit in NY state, see above).

**BOTTOM LINE:** Committee members present believe the vaccine is neither safe nor effective. Committee members present believe DoD did not, and does not, want to know the truth about the impact of this vaccine on either the health of troops or retention. Mr. Shays and Mr. Burton believe that DoD has deliberately misled, if not lied outright, to both Congress and Servicemembers on these issues. Finally, the committee members present all felt that the program was causing a crisis of confidence in military leadership, and should be stopped on that basis alone.